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Application No.: 10/081,555
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Atty. Dkt. No. SALK2270-5
(088802-5212)

Remarks

The present invention is based on the discovery and characterization of a new class of receptors that are part of the steroid/thyroid hormone superfamily of receptors, a representative member of which has been designated SXR (or "steroid X receptor"). Specifically, the present invention is directed to screening assays for determining whether a test compound, or a combination of test compounds, will modulate the activity of SXR polypeptide(s). Invention assays comprise contacting a host cell line containing a SXR receptor polypeptide with one or more test compound(s) in an appropriate culture medium, wherein the host cell line further contains a reporter vector comprising a promoter that is operable in the cell line operatively linked to a SXR response element for activation thereof, and DNA encoding a reporter protein operatively linked to the promoter for transcription of the DNA. Invention assays further include determining whether the reporter protein is present (i.e., expressed by the cell line), wherein a determination that the reporter is present indicates that the test compound activates the SXR polypeptide (i.e., an agonist), and a determination that the reporter is not present in the assay indicates that the test compound does not activate the invention SXR polypeptide (i.e., not an agonist).

By the present communication, claims 4, 33, 34 and 36 have been amended to define Applicant's invention with greater particularity. No new matter has been introduced by the subject amendments as the amended claim language is fully supported by the specification and original claims. Upon entry of the amendments submitted herewith, claims 2-5, 27-29, 32-40 remain pending, with claims 4, 32-34, 36 and 37 under active prosecution (while claims 2, 3, 5, 27-29, 35, 38, 39 and 40 have been withdrawn from consideration pursuant to a previous restriction requirement). The present status of all claims in the application, and current amendments thereto, is provided in the Listing of Claims presented herewith beginning on page 2.

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Double Patenting

The provisional rejection of claims 4, 33, 34 and 36 under the judicially created doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 1 and 7 of copending Application No. 10/302557 is acknowledged. This issue will be addressed in due course pending resolution of all other issues in the case, e.g., by submission of a terminal disclaimer or other action as may be appropriate.

The Rejection under 35 U.S.C. § 112, First Paragraph

The rejection of claims 4 and 32 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement, is respectfully traversed. As acknowledged by the Examiner, "the specification discloses representative species from a subgenus of response elements; *i.e.* SXR response element" (see p. 5, lines 10-12 of the Office Action). As amended, claim 4, step (b) recites "a SXR response element." It is respectfully submitted to be clear that Applicants were in possession of the invention as currently claimed, at the time the application was filed, as required by 35 U.S.C. § 112, first paragraph. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

The Rejection under 35 U.S.C. § 112, Second Paragraph

The rejection of claims 4, 32, 33, 34, 36 and 37 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite, is respectfully traversed. Specifically, Applicants respectfully disagree with the Examiner's assertion that the limitation of "said SXR response element" in claim 4 line 10 allegedly has "insufficient antecedent basis" (see p. 6, lines 1-2 of the Office Action). The Examiner's attention is directed to claim 4, step (b), as amended herein, where explicit antecedent basis is provided for the phrase "said SXR response element," as that term is used throughout the claims. Applicants respectfully submit the claims particularly point out and

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distinctly claim the subject matter which Applicants regard as the invention. Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Conclusion

In view of the above amendments and remarks, reconsideration and favorable action on all claims are respectfully requested. In the event any matters remain to be resolved in view of this communication, the Examiner is encouraged to contact the undersigned so that a prompt disposition of this application can be achieved.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

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By 

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